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Assaf Govari

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04/14/2011

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EXAMINER

SMITH, FANGEMONIQUE A

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/882,126
Filing Date: June 15, 2001
Appellant(s): GOVARI, ASSAF

Paul J. Esatto, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 24, 2011 appealing from the Office action mailed June 24, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-21.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

REJECTIONS.” New grounds of rejection (if any) are provided under the subheading “NEW GROUNDS OF REJECTION.”

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant’s brief.

(8) Evidence Relied Upon

5,405,337	Stern et al.	04-1995
6,752,804	Simpson et al.	06-2004
6,334,093	More	12-2001
5,833,608	Acker	11-1998
5,638,418	Douglass et al.	06-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 1-5 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 5,405,337) in view of Simpson et al. (U.S. Patent Number 6,752,804) and in further view of More (U.S. Patent Number 6,334,093).

In regard to claims 1-5 and 9-15, Stern et al. disclose a tissue heating and ablation system which upon use employs an energy emitting electrode to heat tissue. The system upon use further includes a method for measuring temperature at a site of interest within a patient comprising steps of providing a medical device and placing the medical device within the patient at the site of interest (col. 1, lines 48-67; col. 2, lines 1-49). Stern et al. disclose thermal mapping techniques employed to determine temperature curve coordinates. Stern et al. disclose upon use of the system a voltage is measured at the site of interest and a temperature measurement is taken (col. 5, lines 10-64). Stern et al. disclose the temperature is determined based on an algorithm which includes a resistance value obtained (col. 5; col. 6, lines 1-35). Upon use, the Stern et al. device further includes generating an externally applied field at the patient wherein the frequency of the generator signal is different than the temperature measurement signal. As described, Stern et al. disclose the features of the Applicant's invention as described above. Although Stern et al. discloses thermal mapping and techniques which indicate position of the medical device, Stern et al. do not specifically disclose the use of a position sensor. Simpson et al. disclose a catheter having a plurality of electrodes, each with multiple thermal sensors attached and used to position the electrodes proximal to biological tissue of interest (Abstract). The plurality of sensors used with the Simpson et al. device provide temperature readings and position determination of the catheter (col. 3, lines 53-67; col. 4, lines 1-18). Simpson et al. further disclose positioning the thermal sensors at the electrode tissue interface to provide sufficient electrical energy to the site

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of interest without overheating. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue heating and ablation system, similar to that disclosed by Stern et al., to include a position and temperature sensor which determines the temperature at the position sensor, similar to that disclosed by Simpson et al., to provide information regarding the location of the device while enabling the device to be accurately positioned at the target site. The combined references of Stern et al. and Simpson et al. disclose features of Applicant's invention as described above. The combined references do not disclose providing a resistance drift factor to the resistance value. More discloses a method and apparatus for measurement of temperature differences. The More patent discloses a device which accurately resolves extremely small differences in electrical signals by incorporating a drift compensation factor upon measurement of differences in a physical variable such as temperature. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue heating and ablation system, similar to that disclosed by the combined references of Stern et al. and Simpson et al., to include a resistance drift factor, similar to that disclosed by More, to improve the accuracy of the results obtained while maintaining the functionality of the device.

3. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 6,241,724) as modified by Simpson et al. (U.S. Patent Number 6,752,804) in view of More (U.S. Patent Number 6,334,093) and in further view of Acker (U.S. Patent Number 5,833,608).

In regard to claims 6-8, the combined references of Stern et al., Simpson et al., and More disclose a method for measuring temperature at a site within a patient during a medical

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procedure which includes the features of the Applicant's invention as described above. The combination further describes the medical device being capable of determining a temperature value and temperature sensitivity based on the resistance value. The combined references further disclose performing an ablation procedure at the site with the medical device, however the combined references fail to specifically disclose the use of an AC generator signal to apply a magnetic field to the patient. Acker discloses a magnetic positioning and orientation determining system which uses magnetic fields to deduct the position and orientation of a probe. The system of the Acker patent is used to perform ablation procedures. The device includes a signal generator, which delivers an AC signal to the distal tip of the device. Operation of the device further includes transforming the AC signal into a DC signal upon utilizing a synchronous detector. The generator signal of the Acker device is capable of operating at 3KHz with the temperature measurement signal at 4Hz. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to include an AC generator and synchronous detector system, similar to that disclosed by Acker, to deliver an AC signal to a medical device, similar to the device described in the combined references of Stern et al., Simpson et al., and More, as a way to provide a means for superimposing the probe onto a separately acquired image to display the position and orientation of the probe with respect to the patient.

4. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 6,241,724)) as modified by Simpson et al. (U.S. Patent Number 6,752,804) in view of More (U.S. Patent Number 6,334,093) and in further view of Douglass et al. (U.S. Patent Number 5,638,418).

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In regard to claims 16-21, the combined references of Stern et al., Simpson et al., and More disclose a method for measuring temperature at a site within a patient during a medical procedure. The combination does not specifically disclose providing a sensitivity drift factor to the temperature value when executing the algorithm. Douglass et al. disclose a system and method that is used to detect temperature. The method includes including an error term to simulate possible drift of resistance values. The system of the Douglass et al. patent uses the resistance drift coefficient during its processing step, which is stored by a memory device of the system. Douglass et al. further disclose a temperature coefficient introduced to adjust the temperature measurement according to the temperature sensitivity of the device in operation. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to apply correction factors, similar to those disclosed by Douglass et al., to an algorithm used to measure temperature similar to the one used by the combined references of Stern et al., Simpson et al., and More, in order to improve the accuracy of the calculated measurement and reduce sources of variability.

(10) Response to Argument

Applicant argues the prior art references fail to disclose a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor and determining position and/or orientation coordinates of the position sensor based on the signals provided by the positions system using a location system. Examiner respectfully disagrees. The combined references as described in the previous office action disclose a medical system which, upon use, provides determination of temperature and position

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at a site of interest. The sensors disclosed by Simpson et al. include signals which assist with determining the position of the sensors (col. 3, lines 53-67; col. 4, lines 1-18). The combined references disclose a system which also measures the voltage of the electrodes which are coupled with the sensors of the device; As well as the resistance or thermal resistivity at the site.

Examiner submits the combined references as described in the rejection above meet the limitations of the claim to provide signals used in determining position and/or orientation of the sensor.

Applicant argues the prior art references fail to disclose using the information gathered from the device to adjust the position of the sensor. Examiner respectfully disagrees. The combined references teach using the data gathered from the sensors to provide additional information which may aid in deciding whether to adjust the position or orientation of the device relative to the tissue (Simpson, col. 4, lines 20-28). Examiner submits the combined references as described in the rejection above meet the limitations of the claim to provide information to user to determine whether or not to adjust the position and/or orientation of the sensor.

Applicant argues the prior art references fail to disclose gaining the measurements within a sensitivity. Examiner submits the sensitivity has not been specified to any particular sensitivity and has interpreted this limitation in its broadest most reasonable meaning to refer to the device and its ability to register small amounts of change. Gaining various readings which differ according to the position of the device would assist in determining the sensitivity of the device to its position. The combined references disclose a system which provides different measurements according to the positioning of the device, therefore meeting the limitations of the claim.

Additionally, although not specified in the claims, the specification discloses the temperature

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sensitivity as desirable information gained from the device. The prior art references disclose the system developing a temperature gradient which determines the temperature sensitivity at different target areas. The system as described by the combined references as described above determines the temperature sensitivity of the device, therefore meeting the limitations of the claim.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Fangemonique Smith

/Fangemonique Smith/

Examiner, Art Unit 3736

Conferees:

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/Jeffrey G. Hoekstra/

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